Section 11 510(k) Device Summary

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K011389 .

Submitter	Canterbury Health Ltd Hagley Avenue Christchurch New Zealand Phone (+643) 364 0546 FAX (+643) 364 0545
Contact Person	Maurice Owen, Section Head, Molecular Pathology Lab.
Date of Preparation	3 May 2001
Device Name	Hemoglobin F & A2 Control
Classification	Class II, JCM
Equivalent Device	Lyphochek Hemoglobin A2 Control, Bio-Rad Laboratories. (510(k) = K911347)
Description of Device	The Hemoglobin F & A2 Control is a two level hemoglobin control. Level 1 has an HbF of about 2.0%, and an HbA_2 of 2.5 – 3.2%. Level 2 has about 6.0% HbF and 6.0%. HbA_2. They are intended as a quality control material for analytical HPLC based methods for quantitation of HbF and HbA_2. They are lyophilized in glass vials with screw top caps. They are prepared from normal adult human blood and human cord blood. The source blood is tested and found to be non-reactive for Hepatitis B surface antigen, Hepatitis C antibody, antibodies against human immunodeficiency virus (HIV) types 1 & 2, and Syphilis (RPR and TPHA).

Purified HbA_2 is obtained from adult lysate by ion exchange chromatography. It is blended with cord lysate and adult lysate to give the target levels.

The controls are reconstituted with distilled water or a reconstitution solution comprising the biocide sodium azide (0.09%). The reconstitution volume is between 0.25 mL and 0.5 mL. The controls reconstitute in 10 minutes with occasional swirling, and are stored at 2° - 8°C.

Intended Use of Device

The Hemoglobin F & A2 Control is intended for use as a quality control material to monitor the precision of laboratory testing procedures for HbF and HbA_2 quantitation. The control is designed primarily for high performance liquid chromatography (HPLC) based analyses, but is also suitable for use in electrophoresis based procedures.

The use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. The two levels of controls allow performance monitoring within the clinical range.

The measurement of an elevated HbA_2 blood level is a most important diagnostic test to identify carriers of the β-thalassaemia trait. The estimation of the relative amount of HbF is an important aspect in the diagnosis of homozygous β-thalassaemia in all its forms. It is also necessary for the diagnosis of the homozygous and heterozygous states for δβ-thalassaemia and the different varieties of hereditary persistence of fetal hemoglobin (HPFH).

The controls are for in vitro diagnostic use only and should not be used past the expiry date. They are not intended to be used as standards or calibrants.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Maurice Owen, Ph.D.
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JUN 2 1 2001

Re: K011389
Trade Name: Hemoglobin F & A2 Control
Regulation Number: 21 CFR § 864.7415
Regulatory Class: II
Product Code: JCM
Dated: June 11, 2001
Received: June 13, 2001

Dear Dr. Owen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 10 Statement of Indications for Use

10.1 Device Name

Hemoglobin F & A_2 Control

10.2 Indications for Use

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(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011389/S1